Remarks

Reconsideration and allowance of this application are respectfully requested, in view of the above amendments and the following comments.

If the above amendment is entered, claims 1-3, 7, 8 and 14-17 will be pending in this application, with claims 1 and 17 being independent claims. Claims 4-6 and 9-13 have been cancelled. New claims 14-17 are being added to provide a scope of protection commensurate with the original disclosure.

Applicant wishes to express his appreciation for the courtesies extended to Applicant's representatives during the personal interview with Examiner Meller that was held on September 11, 2003.

Statement of Substance of Interview

Pursuant to the requirement in the Interview Summary dated September 11, 2003, Applicant submits this statement of the substance of the personal interview conducted on that date.

As stated in the Interview Summary, all of the claims that are of record were discussed. In addition, Applicant's proposed claim amendments were also discussed. While a definitive agreement was not reached, the Examiner indicated that he would give further appropriate consideration to Applicant's proposed amendments and arguments if they were also presented in an Amendment After Final Rejection, as is here being done.

The Section 112 Rejections

Claims 9, 10, 12 and 13 were rejected under §112, first paragraph. The Examiner asserted that the specification does not provide support for a claim recitation of the total elimination of mastitis. Claims 9, 10, 12 and 13 were also rejected under §112, second paragraph for their use of the phrase "dairy cow that exhibits an increased number

of somatic cells in her milk." That phrase was said to be confusing, therefore making the claims indefinite.

While Applicant does not necessarily agree with either of these contentions, all of those claims have been cancelled, thereby rendering the rejections moot.

The Present Claim Amendments

After entry of the above amendment, claims 1-3, 7, 8, and 14-17 remain in the application. Claim 1 has been amended to recite a method of treating a lactating ruminant the milk of which contains a concentration of somatic cells that is symptomatic of mastitis. The method comprises the step of administering phytase to the ruminant in an amount sufficient, and for a time sufficient, to lower the somatic cell concentration of the ruminant's milk to a level that is below that which is symptomatic of mastitis. Support therefor is found, for example, in Examples 1-3 (pages 8-11 of the specification), in which such a treatment is described.

As recited in new claim 14, the concentration of somatic cells in the milk of the lactating ruminant is more than 2.5×10^5 cells/ml prior to treatment. Support therefor is found at page 9 (first paragraph) of the specification, where it is disclosed that 65 Holstein lactating cows having "a number of somatic cells above 25×10^4 cells/ml exhibiting light symptoms of mastitis" were treated with phytase for four weeks.

New claim 15 recites that the administration of the phytase is continued at least until the concentration of somatic cells in the milk is less than 2×10^5/ml. This finds support in Example 1 (pages 8 and 9) wherein, after two weeks of phytase administration, the somatic cell content had dropped to 1.53×10^5 cells/ml.

New claim 16 recites that the administration of the phytase is continued at least until the concentration of somatic cells in the milk has dropped to less than 1×10^5

cells/ml. This, too, is supported by Example 1, wherein, after four weeks of administering phytase, the somatic cell level dropped to 0.87 x 10^5 cells/ml.

New claim 17 recites that a dairy herd of lactating ruminants has its milk pooled and analyzed and, when it is determined that the milk has a concentration of somatic cells that is symptomatic of mastitis, that phytase is administered to the herd in an amount sufficient, and for a time sufficient, to lower the somatic cell concentration of the herd's pooled milk to a level that is below that which is symptomatic of mastitis. Support for this claim also is found in Example 1 (page 8), in which it is said that "[m]ilk taken from all cows was combined together and then tested for its components every two weeks."

The First Section 103(a) Rejection

Claims 1-3, 7-10, 12 and 13 were rejected as allegedly being obvious over Lyons, Clarkson et al., Morgan et al., or Bedford et al. in view of Edwards and Chinese Patent No. 1135297 (Lu). Applicant submits that the claims now present, after entry of the above amendment, are obviously patentable over these six references.

Lyons

Lyons suggests that the enzyme phytase normally is present in the gut of some livestock animals, where its function is to release the organically-bound phosphorous that is present in the phytin in cereal feeds. Lyons, page 7. In monogastrics, however -- e.g., pigs and poultry -- the enzyme is lacking. *Id.* Therefore, a considerable quantity of inorganic phosphorous, e.g., dicalcium phosphate, traditionally has been added to pig and poultry feeds. *Id.* This creates the problem of phosphates in the manure finding their way into surface and ground water sources. *Id.*

Lyons reports that in an effort to reduce this phosphate pollution of waterways and the like, phytase has been added to feed for pigs and poultry, in place of

inorganic phosphorous sources. He states that test trials have been successful, in that the phosphorous bound up in the phytin in the cereal of the feed has been released and has been observed to be absorbed into the bloodstream, as measured by increases in blood phosphorous and, subsequently, in bone. *Id.*, pages 7-8.

Ruminants, such as cows, are not monogastric. By definition a ruminant is a "suborder (Ruminantia) of even-toed hoofed mammals (as sheep, giraffes, deer, and camels) that chew the cud and have a complex 3- or 4-chambered stomach." Webster's Ninth New Collegiate Dictionary. Therefore, there is absolutely no teaching or suggestion in Lyons to supplement the feed of any *ruminants* with phytase, let alone the feed of a lactating ruminant the milk of which has a somatic cell concentration that is symptomatic of mastitis.

Clarkson et al.

Clarkson et al. relates to the use of the enzyme xylanase in cereal-based animal feeds to enable the animals to digest such feeds more efficiently. The disclosed purpose of including xylanase is to improve the Feed Conversion Ratio (FCR) of a feed for a growing animal without increasing its cost per unit weight. Col. 1, lines 60-67. Clarkson et al. disclose a particular xylanase that is better able to withstand the high temperatures involved in processing the feed, which are necessary in order to kill any harmful bacteria in it and to shape the feed into durable cubes and pellets. Col. 2, line 60 - col. 3, line 9; col. 4, lines 1-27; and col. 9, lines 16-26.

Clarkson et al. state that cereal-based feed that contains their thermostable xylanase "may be provided to animals such as turkeys, geese, ducks, sheep and cows. It is however particularly preferred that the feed is provided to pigs or to poultry, and in particular, broiler chickens." Col. 4, line 64 - col. 5, line 1. (Sheep and cows are ruminants. The rest of the listed animals are not.)

The patentees go on to say that their feed may also "include other enzyme supplements such as one or more of β-glucanase, glucoamylase, mannanase, α-galactosidase, phytase, lipase, α-arabinofuranosidase, protease, α-amylase, esterase, oxidase, oxido-reductase and pectinase." Col. 5, lines 49-54. That is the only mention of phytase in Clarkson et al. The reference makes no suggestion as to *why* one might wish to also include phytase in the xylanase-containing feed. Thus, Clarkson et al. is a far cry from a teaching to administer phytase to lactating sheep and cows the milk of which contains a level of somatic cells that is symptomatic of mastitis, in an amount, and for a time, sufficient to lower the milk's somatic cell content to a level below that which is symptomatic of mastitis.

Both in the last Office Action and during the September 11 interview, the examiner has indicated that the rejection over Clarkson et al. is bottomed on the notion that if a farmer feeds all of his cows a phytase-supplemented feed, then, "since many cows develop mastitis regularly" (Office Action, page 3), it is inevitable that some of the farmer's cows will be consuming the phytase-based feed at a time when they have mastitis. In other words, this is an inherency rejection. But on the present record it is improper.

Applicant's claimed process of treating a lactating ruminant the milk of which has a somatic cell content that is symptomatic of mastitis represents a new use for phytase-enhanced animal feeds. As explained by the Court of Customs and Patent Appeals in *In re Zierden*, 162 USPQ 102 (CCPA 1969),

> " . . . there is express statutory authority for a patent on a process which is a new use of a known process, composition of matter, or material, 35 U.S.C. 100(b) and 101, provided, of course, the process predicated on the new use is new and unobvious and not subject to a statutory one-year time bar, 35 U.S.C. 102 and 103."

Id. at 104.

In *Zierden*, the applicant claimed a method of preventing the deposition of suspended alluvium (e.g., mud, organic matter, fine sand, and rust) from an industrial

heating or cooling water, by adding potassium metaphosphate to the water. The claim was rejected over a prior art French patent that disclosed the addition of potassium metaphosphate to industrial heating and cooling water for the purpose of preventing the deposition of calcium carbonate scale in such systems, but which gave no indication that alluvium deposition (silting up) also could be prevented by the addition of potassium metaphosphate. The Patent Office argued that all industrial waters inherently contain some amount of alluvium and, therefore, that the claimed process would inherently be performed when following the prior art teaching. *Id.* at 105.

The Court of Customs and Patent Appeals reversed the rejection, stating that because the reference did not indicate that the industrial water used in its examples contained any alluvium, it was possible that the treatment disclosed therein could have been performed without inherently preventing alluvium deposition and, therefore, without inherently practicing the claimed method. E.g., the water could have been filtered prior to addition of the potassium metaphosphate. *Id.*

In the present situation, in order for the rejection of Applicant's claims over Clarkson et al. to be appropriate, the hypothetical cow fed with the reference's xylanase-and-phytase-containing feed would have to be both lactating and producing milk having a somatic cell concentration that is symptomatic of mastitis. It is obviously possible that that would *not* be the case. First of all, the cow might not be lactating. Bearing in mind that the special purpose for which Clarkson et al. developed their feed is to bring a growing animal to market weight with the least consumption of feed, it well may be that the farmer who follows Clarkson's suggestion only provides the feed to cows that are being raised for slaughter, not to dairy cows. Moreover, even if the feed is administered to a dairy cow, in order to anticipate the claims the cow would have to be producing milk having a somatic cell concentration that is symptomatic of mastitis. There is nothing said in Clarkson et al. that makes it certain that that would happen, and it is well settled that inherency "may not

be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Hansgirg v. Kimmer*, 40 USPQ 665 (CCPA 1939). *See also, In re Olrich et al.*, 212 USPQ 323 (CCPA 1981).

Under *Zierden*, there simply are not enough specifics in Clarkson et al. for that reference to be a proper basis for an inherency rejection of the present claims. Indeed, this is not even as close a case as was *Zierden*. Here there is no example in the reference of the administration of phytase to a sheep or cow, just the general statement that "[t]he cereal-based feed according to the present invention [which may or may not contain phytase] may be provided to animals such as turkeys, geese, ducks, sheep and cows." And since the sole purpose taught by Lyons for adding phytase to animal feeds applies only to monogastric animals, the most likely result of combining the teachings of Lyons and Clarkson et al. is the supplementation of Clarkson's xylanase-containing feed with phytase only when it is to be used for raising pigs or poultry, not when it is to be used for feeding sheep or cows.

Morgan et al.

Morgan et al. is similar to Clarkson et al., but is even more distant from the present claims. Morgan et al. discloses five other thermostable xylanases, but only suggests using them as a supplement for a cereal-based feed for poultry or pigs. Col. 4, lines 49-52. No mention is made of any ruminants, much less any lactating ruminants the milk of which contains a somatic cell concentration that is symptomatic of mastitis.

The only mention of phytase in Morgan et al. is the suggestion that "[t]he feed provided by the present invention may also include other enzyme supplements such as one or more of β-glucanase, glucoamylase, mannanase, α-galactosidase, phytase, lipase, α-arabinofuranosidase, portease, α-amylase and pectinase." Col. 10, lines 11-15.

Bedford et al.

Bedford et al. has essentially the same relevance as Clarkson et al. Again, the disclosed objective is to create a cereal-based feed for growing animals that will exhibit an improved Food Conversion Ratio. Col. 1, lines 6-18. Bedford et al. teaches the use of a combination of three enzymes: a xylanase, a protease, and a β-glucanase. Once again there is a general statement that "[t]he enzyme feed additive provided by the present invention may also include other enzymes such as one or more of an α-amylase, a glucoamylase, a pectinase, a mannanase, an α-galactosidase, a phytase and a lipase." Col. 8, lines 16-19.

Like Clarkson et al., Bedford et al. states generally that its enzyme-enhanced feeds are "suitable for animals such as turkeys, geese, ducks, pigs, sheep and cows. The feeds though are particularly suitable for poultry and pigs, and in particular broiler chickens." Col. 10, lines 37-40.

There are five numbered examples in Bedford et al. and none involves a ruminant or the inclusion of any phytase in the feed. The only animals used in the examples are broiler chickens, castrated male pigs, and male turkey poults.

Bedford et al. also falls far short of teaching the administration of phytase to a lactating ruminant the milk of which has a somatic cell concentration that is symptomatic of mastitis, let alone doing so in an amount, and for a time, sufficient to lower the somatic cell concentration to a level that is below that which is symptomatic of mastitis.

Edwards

Edwards, here used as a secondary reference, discloses the addition of the combination of (a) a particular derivative of vitamin D_3 and (b) phytase to the feed of "monogastric animals, including but not limited to, humans, swine, [chickens] and other fowl including turkeys, pheasants, and ducks." Col. 6, lines 25-29. The vitamin derivative increases calcium utilization (so less dietary calcium is needed) and the phytase enhances

phytate phosphorous utilization (so less supplemental phosphorous is required in the diet). Col. 4, lines 30-37.

Edwards goes on to say that the same feed compositions are also effective in preventing or treating tibial dyschondropalasia "in a variety of animals including, but not limited to, swine, dogs, rabbits, cattle, fish and other fowl including turkeys, pheasants and ducks." Col. 6, lines 34-41. All of his examples involve the feeding of birds.

This disclosure by Edwards adds nothing of relevance to that of any of the principal references. It certainly provides no incentive or suggestion to administer any of the phytase-containing feeds of Lyons, Clarkson et al., Morgan et al., or Bedford et al. to lactating ruminants the milk of which contains a concentration of somatic cells that is symptomatic of mastitis, much less to do so in an amount sufficient, and for a time sufficient, to lower the somatic cell concentration to a level below that which is symptomatic of mastitis.

CN 1135297

Chinese Patent No. 1135297, also used as a secondary reference, discloses the addition of zinc methionine sulphate to a feed for cultivating bullfrogs. It is said that the feed "saves food and has obvious effect." It appears from the English translation that the reference makes no mention of phytase and says nothing about feeds for any of the animals mentioned in the principal references. CN 1135297 is simply irrelevant to any of the present claims.

The Second Section 103(a) Rejection

Claims 1-3, 7-10, 12 and 13 have been rejected under 35 U.S.C. 103(a) as also being obvious over Edwards in view of CN 1135297.

As mentioned, Edwards discloses that a feed composition containing a particular derivative of vitamin D_3, in admixture with phytase, may be effective in

preventing or treating tibial dyschondropalasia in a variety of animals, including cattle. The examiner contends that if farmers feed their cattle with this composition, some of the cattle will be cows that develop mastitis; therefore, "[t]here will be cows who have mastitis that will be fed the feedstuff and thus the mastitis will be treated. It is also noted that since there will be cows with mastitis that are being treated there will also be cows with an increased number of somatic cells in their milk." Office Action, page 4.

As discussed above, with respect to the first Section 103(a) rejection, in order to be proper, this type of rejection (inherency-based) has to be based upon certainty, not probabilities or possibilities. Edwards does not even mention dairy cows, let alone provide an example of treating such. It is therefore quite possible to fully implement Edwards's suggestion by feeding his composition to *beef* cattle for the prevention of tibial dyschondropalasia, without inherently administering the composition to any lactating cow the milk of which has a concentration of somatic cells that is symptomatic of mastitis.

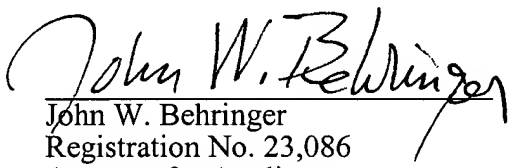
CN 1135297 evidently is relied upon to reject claim 8, which calls for the feedstuff to also comprise zinc methionine sulphate. As mentioned, CN 1135297 discloses a feed additive for bullfrog cultivation that contains zinc methionine sulphate. The reference appears to make no mention of including that chemical in cattle feed or using it to prevent or treat tibial dyschondropalasia. Accordingly, there is no apparent nexus between Edwards and CN 1135297, making the rejection clearly improper.

Conclusion

In view of the above amendments and remarks, Applicant submits that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below-listed address.

Respectfully submitted,



John W. Behringer
Registration No. 23,086
Attorney for Applicant

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

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